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RISK ASSESSMENT CRITICISMS  
Since June 1990

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**CAVEAT:** This document represents a list of statements drawn from various sources. Only the potentially helpful statements have been excerpted here. However, the source documents may contain factual inaccuracies and/or adverse statements. The documents cited herein are maintained in a back-up file for reference; they should be consulted before any of these quotes are used.

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## I. PUBLISHED ARTICLES

1. Anon., "Junk Science," National Review, April 12, 1993 [7/30/93]<sup>1</sup>
  - "Another piece of junk science from the EPA is the notion that thousands of non-smokers die of lung cancer from the smoke of smokers -- a/k/a environmental tobacco smoke (ETS)."
  - "The EPA's recent declaration that ETS is a 'Class A carcinogen' was achieved by a quite shameless abandonment of regular scientific procedures. . . . Though it claimed to have proved' the association by a 'meta analysis' or combining of the existing studies, the EPA simply abandoned the conventional 95 per cent confidence level and applied a 90 per cent test in order to claim the result was statistically significant."
  - "Alvan Feinstein, professor of medicine and epidemiology at Yale medical school, wrote recently in Toxicologic Pathology that the EPA study on environmental smoke 'simply ignored the inconvenient results and emphasized those that are (in a memorable phrase) "helpful."' He said he had been told by a colleague that the EPA report on ETS was 'rotten science' in the worthy cause of getting a smoke-free society."
2. Anon., "Biley Blasts EPA for 'Political' Science," Human Events LI(43): October 26, 1991 [7/30/93]
3. Anon., "Environmental Tobacco Smoke: Science or Politics?," CECCM, March 1993 [7/30/93]

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1. The date in brackets indicates the date on which an item was added to this document. The earliest date to appear in the brackets is July 30, 1993, the date this document was created.

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4. Anon., "EPA Releases Review Draft on ETS and Respiratory Health," TDC Alert!, June 19, 1993 [7/30/93]
5. Anon., Kingsport Times News, Tenn. 1/7/93 [8/20/93]
  - "The Environmental Protection Agency today will foster yet another hoax on the American people as it begins a campaign of public misinformation on the hazards of secondhand smoke."
  - Need copy.
6. Anon., Citizen News, 3/3/93 [8/20/93]
  - "The looseness of the scientific standards of EPA's report and its exaggeration of the risks associated with passive smoke raise once again questions about what is happening to scientific ethics."
  - Need copy.
7. Anon., American Spectator, April 1993. [8/20/93]
  - "In truth, this report is another example of the EPA shaping scientific findings to support its own preconceived policies."
  - "Now that the EPA has lowered the standard of risk, not only can second-hand smoke be classified as a cancer risk but so can ordinary tap water, whose risk factor is twice that of second-hand smoke."
  - Need copy.
8. Anon., The National Review, July 19, 1993 [8/20/93]
  - "The EPA's edict on ETS was accompanied by a weighty tome of junk science, in which almost every known statistical confidence trick is on display."
  - "By the scandalously manipulative standards of the ETS case, the EPA could move immediately to ban chlorination of drinking water, order massively expensive reorganization of electricity service lines (because of the speculative dangers of electro-magnetic fields), and outlaw diesel vehicles and heating systems that use number 2 home heating oil. In all these cases there are already statistical studies that produce risk numbers at least as strong as those used to indict ETS."

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- Need copy.

9. Caldwell, C., "Smoke Gets in Your Eyes," The American Spectator, May 1992 [7/30/93]

- "[T]he EPA, having failed in its attempts to establish clear-cut and readily confirmable proof of the harms of ETS, had used a complicated and irregular scientific route to claim a minimal link."
- "There was obvious selective bias at work in the 1990 EPA risk assessment."
- "The EPA went out on a limb to classify passive smoke as 'Group A: Known human Carcinogen,' even though most of the studies showed no significant risk, some showed a negative risk, and the final risk ratio, after meta-analysis, was a slim 1.28."

10. Clyburn, J., "Smoking Restrictions In Federal Buildings Aren't Fair to Workers," Roll Call, May 31, 1993 [7/30/93]

11. "EPA's Smokescreen," Richmond Times-Dispatch. 1/11/93 [7/30/93]

- "The EPA's report on passive tobacco smoke--bureaucratically known as environmental tobacco smoke (ETS) -- is a case of fudging science to fit a politically correct, pre-determined policy result."
- "In pursuit of greater regulatory authority over indoor air quality, the EPA skewed its assessment of ETS."

12. "EPA's 'Smoking' Gun: More Science Chasing Ideology," The Kentucky Journal of Commerce and Industry. 1/21/93 [7/30/93]

- "What we have at the EPA might be called political science -- science you shape and bend to fit a social agenda."

13. "Final Report Linking ETS, Lung Cancer Prompts Calls for Workplace Bans," BNA National Environment Daily. 1/7/93 [7/30/93]

- "[T]he report will not spur any direct regulatory action from EPA -- the agency lacks such authority for indoor air issues."

14. Fumento, M., "Is EPA Blowing Its Own Smoke? How Much Science is Behind Its Tobacco Finding?," Investor's Business Daily January 28, 1993 [7/30/93]

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- [Re the 90% CI] "'That doubles the chance of being wrong,' explained James Enstrom, a professor of epidemiology at the University of California, Los Angeles."
- "'In most cases, a scientist would never do this sort of thing,' Enstrom said. 'It's surprising that they would try to get away with it.'"
- "'They're using it [90%] so they can get an effect,' Enstrom said. 'They're going all-out to get something they can call significant.'"
- "'In fact, [the one-tailed test] actually reduces the confidence level even further, providing a greater chance of labeling something carcinogenic when it isn't.'"
- "'Said Joel Hay, a health economist at the University of Southern California who teaches statistics, 'In essence, that's more like going to an 85% level, which would triple the chance of a mistake due to chance.'"
- "'If they've done both, then they're obviously reaching for results,' he said."
- "'One problem with slicing the data so thinly as the EPA passive smoke study does is that epidemiology is not an exact science. A single variable unaccounted for can destroy a whole study.'"
- "'EPA Watch's [Bonner] Cohen and other EPA critics think that the passive smoking report is just the latest in a litany of EPA abuses of science to achieve political ends -- most prominently that of enlarging its own authority, especially to gain more control over indoor air regulation.'"
- "'The EPA was not unaware of the fact that the tobacco industry is an extremely appealing target with few allies in the public arena,' Cohen said."
- "'Further, the tobacco industry has cried wolf so many times that it doesn't have any credibility anymore.'"

15. Fumento, M., "Tobacco Industry Challenges EPA Finding," Investor's Business Daily. 6/22/93 [7/30/93]

- [Re: change to 90% CI] "Critics such as Glenn Lammi, chief counsel of the legal studies division at the

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Washington Legal Foundation, said that amounts to 'moving the goal posts during the game.'"

- "'They changed the rules with no public comment and no explanation as to why they did it,' he said."
- "That's a sentiment shared by University of California at Los Angeles epidemiologist James Enstrom."
- "'They're just using it so they can get an effect,' said Enstrom when the EPA announced its findings."

16. Gori, G., "Science, Policy, and Environmental Tobacco Smoke," Presentation, Symposium on Environmental Analytical Chemistry, Jekyll Island, Georgia, June 14-16, 1993 [7/30/93]

17. Gross, A.J., "Workplace Exposure to Environmental Tobacco Smoke and the Reported Risk of Lung Cancer in Nonsmokers," American Statistical Association, Abstract, February 1993 [7/30/93]

18. Heaster, J., "Science or Smoke Screen?," Kansas City Star January 30, 1993 [7/30/93]

- "The tobacco industry may have been a victim of bad science when the Environmental Protection Agency recently declared that passive smoking poses a major threat of lung cancer to non-smokers."
- "There's nothing wrong, of course, with government trying to promote the general welfare. But using tax dollars to finance questionable government efforts to undermine those engaged in legitimate business does not further this constitutional mandate."

19. Hoffman, M., "A Smoking Gun . . . Firing Blanks?," The Washington Times, January 25, 1993 [7/30/93]

- "[T]he EPA's peremptory attitude notwithstanding, its study is hardly 'unassailable.' In fact, it appears that the EPA manipulated the study and lowered scientific standards to reach a politically desirable conclusion."
- "[T]he EPA should not be treated as an impartial source of scientific truth, because it has similar incentives to argue that ETS is a carcinogen."

20. Hoffman, M.C., "Blowing Smoke," Washington Times. 7/1/93 [7/30/93]

- "It just so happens that the tobacco industry is correct."

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- "The EPA apparently manipulated their secondhand smoke (also known as Environmental Tobacco Smoke, or 'ETS') study to reach a politically desirable conclusion."
- "In its most egregious breach of scientific ethics, the EPA ignored standard statistical principles, lowering the 'confidence interval' (which statisticians use to compensate for the inevitable errors that occur in such studies) from the standard 95 percent to 90 percent. Although this may seem like a marginal difference, it is actually a major leap; it doubles the probability that the result of the study is due to chance."
- "[I]t is hardly necessary to empower federal regulators and dispose of scientific standards in order to address the issue, Common sense, good manners, and voluntarily created 'smoking areas' are infinitely preferable to the keystone commissars at EPA."

21. Huber, G., et al., "Passive Smoking: How Great a Hazard?", Consumer's Research, 74(7), July, 1991: 10-34 [7/30/93]

22. Izumi, L.T., "No-Smoking Bill Example of Government 'Nannyism', " Sacramento Sunday Union, March 28, 1993 [7/30/93]

- "[A] careful inspection of EPA's methodology finds holes aplenty."
- "[B]y combining the studies, EPA was able to make the numbers support their anti-ETS position."

23. Katzenstein, A.W., "Environmental Tobacco Smoke and Lung Cancer Risk: Epidemiology in Relation to Confounding Factors," Environment International 18: 341-345, 1992 [7/30/93]

24. Katzenstein, A.W., "Implications for Disease Misclassification in Epidemiological Studies of Lung Cancer Risk for Nonsmokers Exposed to Environmental Tobacco Smoke," Environment International, 19: 211-212, 1993 [7/30/93]

25. Keane, D.F., "Smoking in the Workplace: A Choice?", Presentation to Virginia Manufacturers Association, Employment and The Law Seminar, May 11, 1993 [7/30/93]

26. Kilpatrick, S.J., "The Epidemiology of Environmental Tobacco Smoke (ETS) and the Weight of Evidence Argument," International Surgery 77: 131-133, 1992 [7/30/93]

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27. Layard, M.W., "The Background Adjustment in Risk Assessment of Environmental Tobacco Smoke and Lung Cancer," Environment International 18: 453-461, 1992 [7/30/93]
28. Lee, P.N., "Evaluation of Epidemiological Studies on Environmental Tobacco Smoke and Lung Cancer from a Statistical Perspective," Pollution Atmospherique, pp. 75-82, April-June, 1992 [7/30/93]
29. Lee, P.N., "An Assessment of the Epidemiological Evidence Relating Lung Cancer Risk in Never Smokers to Environmental Tobacco Smoke Exposure," Environmental Tobacco Smoke, H. Kasuga, ed., Springer-Verlag, New York-Berlin-Heidelberg, 1993: 28-70 [7/30/93]
30. Mangan, J.F., "Will Passive Smoking Claims Burn Your Bottom Line?," Best's Underwriting Newsletter 22(2): February 1993 [7/30/93]
31. Mangan, J.F., "Extinguishing Claims From Passive Smokers," Best's Review, May 1993 [7/30/93]
  - "Adoption of such a significant procedural change [from 95% to 90%] on a highly controversial issue may raise serious questions about the validity of their conclusions."
  - "The scientific evidence supporting the risk assessment is the least persuasive EPA has ever accepted and there already are indications that new research may discredit its findings."
32. Mark, J., "Smoky Science: EPA Subverts Nobility of the Cause," Phoenix (Arizona) Gazette [7/30/93]
  - "The EPA report doesn't qualify. It's not good science."
  - "Science is a servant of truth, not a tool of political correctness or popular causes, no matter how noble those causes might be. If smoking is to be the object of a crusade, make it a good, old-fashioned political crusade. Don't pervert the science to justify the politics."
33. "Myron Kandel Examines EPA-Tobacco Industry Battle," CNN--Moneyline. 6/22/93 [7/30/93]
  - "Now, I don't pretend to be able to judge the scientific merits or demerits of the tobacco industry's complaint. But any business that believes it's been a victim of

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government abuse deserves the right to present its case in court."

34. Pack, T., "Industry's Attacks Unlikely to Affect Smoking Trends," Lexington Herald-Leader. 6/28/93 [7/30/93]
  - "The tobacco industry's suit raises some valid questions about the EPA's procedures."
35. Perkins, J., "Smoke Signals Taxes, Harsh Rules Go Too Far in Crusade to Snuff Out Habit," The San Diego Union-Tribune March 12, 1993 [7/30/93]
  - "This very-near insidious anti-smoking anti-smoking crusade was given a recent boost by a shockingly irresponsible Environmental Protection Agency report."
  - "EPA's finding is a clear example of bad science being used to justify politically correct policy."
36. Philip Morris Press Packet, "Statement of Philip Morris USA," U.S. EPA Risk Assessment on ETS, January 6, 1993 [7/30/93]
37. "Puff Science at EPA," The Washington Times. 6/29/93 [7/30/93]
  - "[A]t an April 1991 press conference, Dr. Lippman [sic] was critical of the claim that it causes 3,700 cases of lung cancer: The evidence, he said, is too weak to support such a claim."
  - "Dr. Lippman explained that the report was not 'breaking new ground.' The possibility of getting cancer from second-hand smoke is 'a small added risk, probably much less than you took to get here through Washington traffic' -- as he was quoted in The Washington Times by Ron Taylor."
  - "In other words, it's a risk but not a very big risk."
  - "What the tobacco-industry suit may do is provide a glimpse of politically correct science in the making at EPA. The charges in the filing are serious and more than a little damaging to the agency if proved."
  - "Excessive regulation and poor science make terrible government. If the suit filed last week prevails, we will have reached the pass at which the tobacco industry has greater credibility on this health issue than the EPA. That would speak volumes about the state of government

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'science,' and those volumes will be useful to smokers and nonsmokers alike."

38. Rodgman, A., "Environmental Tobacco Smoke," Regulatory Toxicology and Pharmacology 16: 223-244, 1992 [7/30/93]
39. Samuel, P., et al., "Facts Catch Up With 'Political' Science," Consumers' Research, May 1993 [7/30/93]
  - "As stated by EPA itself in a recent report, its use of unusual scientific methods on this subject -- lowering the statistical standard used to estimate risk -- 'is based on the a priori hypothesis . . . that a positive association exists between exposure to ETS and lung cancer.'"
  - "This relatively low degree of risk was acknowledged by Dr. Morton Lippmann, head of the EPA risk assessment panel, when announcing results of its analysis. Lippmann told reporters attending a press conference they had exposed themselves to greater risk driving across town in Washington traffic to attend the meeting than any hazard from ETS."
  - "In effect, this [change in CI's] doubled the chance that the numbers cited were merely the result of random variation, but it also meant that the data could be treated as more persuasive."
40. Shanahan, J., "Smoking Under the Gun," The Washington Times, December 6, 1992 [7/30/93]
  - The SAB's "recommendation was not based on standard scientific methods. Instead, it was based on methods specifically devised by the EPA to yield the desired result: that secondary smoke causes cancer."
  - "[I]t is important whether EPA's science advisory board based its recommendation on sound science -- or whether it was acting politically."
  - "If science is to be credible and valuable to the public-policy process, it must pass the test of critical scrutiny, whether we like the answers or not."
41. Shanahan, J., Phoenix Gazette, 12/7/92 [8/20/93]
  - "As a non-smoker who intensely dislikes the smell of other people's fumes, and as the father of a newborn daughter, I have strong objections to having my family

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subjected to secondary smoke. Yet, ironically, I cannot in good conscience condone EPA's crusade."

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42. Smith, L.N., "Weird Science," Orange County Register, May 23, 1993 [7/30/93]

- "And what the media didn't say about recent EPA 'discoveries' on the effect of 'secondhand smoking' is that, although some harm to non-smokers may have been detected, it was less (by an order of two of magnitude) than that associated with frying bacon a couple times a week or keeping a pet bird."

43. "Smoke and Mirrors," Editorial, The Detroit News, January 14, 1993 [7/30/93]

- "[T]he methods employed by EPA to achieve it were scientifically underhanded."
- "In this instance, as with too many others, EPA appears to have abandoned accepted scientific methods to further a politically correct agenda."

44. "Smoke Screen," Richmond Times-Dispatch. 7/2/93 [7/30/93]

- "The EPA report was clearly intended to support further regulation of smoking. The fly in the EPA's ointment is that several large-scale medical studies do not link secondhand smoke with lung cancer. So to conclude that secondhand smoke is a Group A carcinogen, the EPA had to cull its data."

45. Switzer, P. and Layard, M.W., "Problems In The Assessment Of Lung Cancer Risk From Exposure To Environmental Tobacco Smoke," Environmental Tobacco Smoke, H. Kasuga, ed., Springer-Verlag, New York-Berlin-Heidelberg, 1993: 108-119 [7/30/93]

46. The Tobacco Institute, "Tobacco Update: An Information Resource Profiling Current Smoking Issues for Journalists," January 6, 1993 [7/30/93]

47. Tweedie, R.L., and Mengersen, K.L., "Lung Cancer and Passive Smoking: Reconciling the Biochemical and Epidemiological Approaches," British Journal of Cancer 66: 700-705, 1992 [7/30/93]

48. "Something to Chew Over in the Oval Office," R. Emmett Tyrrell, Jr., The Washington Times. 2/7/93 [7/30/93]

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- "In truth, this report is another example of the EPA shaping scientific findings to support its own preconceived policies."

49. "Using Standard Scientific Methods Essential in Public Policy Issues," Tyler (TX) Courier Times. 12/30/92 [7/30/93]

- "[I]t [is] extremely important as to whether EPA's science advisory board based its recommendations on sound science, or whether it was acting politically."
- "To be credible and valuable to the public policy process, science must pass the test of critical scrutiny, whether the answers are popular or not."

50. "Will Passive Smoking Claims Burn Your Bottom Line?" Best's Underwriting Newsletter. 2/93 [7/30/93]

- "[Y]ou might be tempted to dismiss [TI's] criticism as nothing more than industry propaganda. Some of their criticism, however, stands on a firm foundation and may influence judicial evaluation of future expert testimony based on EPA's findings."
- "The scientific evidence supporting the risk assessment is the least persuasive EPA has ever accepted, and there are already indications that new research may discredit their findings."

51. Wehner, A.P., President, Biomedical and Environmental Consultants, Inc., Investor's Business Daily, 1/28/93 [8/20/93]

- "I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

52. Williams, W., "Tobacco Smoke Report Employs Weird Science," Detroit Free Press. 6/30/93 [7/30/93]

- "When the EPA classified environmental tobacco smoke (or secondhand smoke) as a carcinogen, putting it in the same category as benzene and asbestos, its actions were based on statistical methods that would earn an F for a sophomore statistics student, if not expulsion for intellectual dishonesty."
- "Had it stuck to the minimally acceptable 95 percent, assignment of secondhand smoke as a 'Group A carcinogen' would have been impossible. This is gross dishonesty,"

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and all EPA bureaucrats involved should be summarily fired."

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II. CRITICAL COMMENTS SUBMITTED TO THE EPA PUBLIC DOCKET (1990) AND THE SCIENCE ADVISORY BOARD (1992)

1. Adlkofer, F., "Re: Draft of the EPA Report on Passive Smoking," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
2. Aviado, D.M., "Non-epidemiologic Studies on Potential Pulmonary Carcinogens in Environmental Tobacco Smoke: A Critique of the Environmental Protection Agency's Designation of Environmental Tobacco Smoke as a Group A Carcinogen," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
3. Bridges, J.W., "Health Effects of Passive Smoking -- Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
4. Brown, R.C., "Comments on EPA Review Drafts 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' and 'Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
5. Butler, W.H., Letter submitted to U.S. EPA public docket, 1990 [7/30/93]
6. Butler, W.J., "Review of: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children (Review Draft; May, 1990)," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
7. Butler, W.J., "Review of: Respiratory Health Effect of Passive Smoking: Lung Cancer and Other Disorders (EPA/600-690/006B; SAB review draft; May, 1992)," comments submitted to U.S. Environmental Protection Agency Science Advisory Board Committee Meeting, July 23-24, 1992 [7/30/93]
8. Cerioli, A., "Ref.: EPA Draft on Environmental Tobacco Smoke, E.T.S.," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
9. Chanter, D.O., "Comments on EPA Document EPA/600/6-90/006B; 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July, 1992 [7/30/93]
10. Clayton, J.W., "'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in

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Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]

11. Colucci, A.V., "Re: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children (External Review Draft)," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
12. Crepat, G., "A Commentary on issues Relating to Lung Cancer in the 1990 EPA External Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
13. Daniel, J.W., "Re: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' EPA/600/6-90/006A; May, 1990; Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
14. Daniel, J.W., "Re: 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders.' EPA/600/6-90/006B: May, 1992; Review Draft," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 2, 1992 [7/30/93]
15. DiNardi, S.R., "Comments on the EPA Review Draft, Health Effects of Passive Smoking," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
16. Ecobichon, D.J., "Re: 'Health Effects of Passive Smoking' EPA/600/06-90/006A," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
17. Faccini, J.M., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
18. Faeder, E.J., "Re: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children (External Review Draft)," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
19. Feuer, G., "Comments on the Review Draft Released by the Environmental Protection Agency Entitled 'Health Effects of Passive smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
20. Flamm, W.G., "Review of the Draft EPA Document Entitled 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 1, 1992 [7/30/93]

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21. Fleiss, J.L., and Gross, A.J., "Critique of the Draft EPA Document Entitled 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
22. Furst, A., "Comments on the Document: U.S. EPA Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children. (EPA/600.690/006A; May 1990)," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
23. Gibbons, J.D., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
24. Goodfellow, H.D., and Eyre, S., "Assessing Exposures to Environmental Tobacco Smoke as It Pertains to: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
25. Gori, G.B., "A Comment on 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' EPA/600/6-90/006a, May 1990," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
26. Gori, G.B., "Statement Addressed to the Indoor Air Quality and Total Human Exposure Committee in Reference to the Review of EPA's Draft Document 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders.' (EPA/600/6-90/006B), May 1992," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 6, 1992 [7/30/93]
27. Gorrod, J.W., "A Commentary on Specific Issues Raised in the EPA MAY 1990 External Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
28. Gross, A.J., "Comments by Alan J. Gross, Ph.D., on Chapters 3 and 4 of the EPA Draft Document: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
29. Holcomb, L.C., "Comments in Regard to: Draft EPA Documents Entitled (1) 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' (2) Environmental Tobacco Smoke: A Guide to

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Workplace Smoking Policies," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

30. Hood, R.D., "Comments on the Draft Document Entitled 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, June 30, 1992 [7/30/93]
31. Hood, R.D., Witorsch, R.J., and Witorsch, P., "Comments on the Draft Document Entitled 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
32. Huber, G.L., "Commentary on EPA Review Draft 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
33. Husting, E.L., "Re: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children (External Review Draft)," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
34. Jonas, K., "Comments: The EPA Review Draft: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
35. Katzenstein, A.W., "The Role of Confounding Factors in Assessing Epidemiological Evidence on ETS and Risk of Lung Cancer," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
36. Kilpatrick, S.J., "Comment on Dr. Hirayama's Record Linkage Study of Japanese Adults in 'Epidemiologic Evidence of Lung Cancer from ETS,' Chapter 3 of the EPA Review Draft 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
37. Layard, M.W., "Comments on the EPA Review Draft 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection agency, June 30, 1992 [7/30/93]
38. Lee, P.N., "'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children.' A Commentary on Issues Relating to Lung Cancer in

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the May 1990 EPA External Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

39. Lee, P.N., "A Commentary on Issues Relating to Lung Cancer in the May 1992 SAB Review Draft," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 1, 1992 [7/30/93]
40. Leslie, G.B., "Comments by George B. Leslie, FRC Path., on May 1990 EPA External Review Draft: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]
41. LeVois, M.E., and Layard, M.W., "Summary of Major Criticisms of EPA's Draft Risk Assessment: Health Effects of Passive Smoking," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
42. LeVois, M.E., "Meta-analysis of ETS Epidemiologic Data Compounds Bias and Overestimates Risk," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 1, 1992 [7/30/93]
43. Magnussen, H., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
44. Malmfors, T., "Re: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
45. Mantel, N., "Commentary: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' EPA Review Draft 5/90," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
46. Mantel, N., "Commentary: 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders' EPA/SAB Review Draft, May 1992," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 6, 1992 [7/30/93]
47. Newell, G.W., Letter in response to Science Advisory Board's request for comment on Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 2, 1992 [7/30/93]

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49. Pedelty, J., "A Response to the EPA Review Draft Document Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
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53. Reasor, M.J., and Will, J.A., "Evaluation of the EPA Draft Report Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
54. Reasor, M.J., "Comments on the U.S. EPA Draft Report Entitled 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July, 1992 [7/30/93]
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56. R.J. Reynolds Tobacco Company, "Before the Science Advisory Board of the United States Environmental Protection Agency: 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,' EPA/600/6-90/006B -- SAB Review Draft, Comments of R.J. Reynolds Tobacco Company," comments submitted

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to Science Advisory Board, U.S. Environmental Protection Agency, July 6, 1992 [7/30/93]

57. Roe, F.J., "Review of EPA Draft Document: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
58. Rutsch, M., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
59. Rylander, R., "Comments on Document Review Draft EPA/600/6-90/006A Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
60. Rylander, R., "Comments on EPA Review Draft 'Respiratory Health, Effects of Passive Smoking: Lung Cancer and Other Disorders,' May 1992," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 3, 1992 [7/30/93]
61. Samanek, M., Letter responding to May, 1992 Review Draft, comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 3, 1992 [7/30/93]
62. Schmahl, D., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
63. Schneider, B., "Statistical Evaluation of the Association Between Environmental Tobacco Smoke (ETS) and Health Risks," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
64. Singh, J., "Comments on the EPA Draft Report on Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
65. Skrabaneck, P., letter submitted to U.S. EPA public docket, 1990 [7/30/93]
66. Springall, A., "Re Review Draft of EPA Report: Ref EPA/600/6-90/006A," comments submitted to U.S. EPA public docket, 1990 [7/30/93]
67. Springall, A., "Re Revised Draft of EPA Report: Ref EPA/600/6-90/006B," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, June 30, 1992 [7/30/93]

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69. Sterling, T.D., "Comments on the Revised EPA Draft: 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 3, 1992 [7/30/93]

70. Sullivan, F.M., "Re: Draft Review of Health Effects of Passive Smoking," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

71. Switzer, P., "Comments on the EPA Review Draft: Health Effects of Passive Smoking," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

72. Switzer, P., "Comments on EPA SAB Review Draft, May 1992 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, June 30, 1992 [7/30/93]

73. The Tobacco Institute, "Comments of The Tobacco Institute on 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children' Review Draft," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

74. The Tobacco Institute, "Comments of The Tobacco Institute on 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,' Review Draft," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 6, 1992 [7/30/93]

75. Theodor D. Sterling and Associates Ltd., "Comments on: 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,' EPA/600/6-90/00683 [sic], SAB Review Draft, May 1992, Chapter Three: Estimation of Environmental Tobacco Smoke Exposure," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 3, 1992 [7/30/93]

76. Todhunter, J.A., "Review of the Draft EPA Document Entitled 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]

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77. Todhunter, J.A., "Re: EPA Review Draft 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,'" comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, June 27, 1992 [7/30/93]

78. Tozzi, J.J., Letter to E. Bretthauer submitting meta-analysis of epidemiologic studies, December 4, 1992 [7/30/93]

79. Tozzi, J.J., Letter to R. Loehr containing comments of Multinational Business Services, Inc. on Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, October 27, 1992 [7/30/93]

80. Tweedie, R.L., "Lung Cancer and Exposure to Environmental Tobacco Smoke: Assessment of Issues Raised in the Review Draft of the Environmental Protection Agency of the United States," comments submitted to U.S. EPA public docket, 1990 [7/30/93]

81. Uberla, K., letter submitted to U.S. EPA public docket, 1990 [7/30/93]

82. Wexler, L.M., "Comments on the EPA Draft Document Entitled 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]

83. Witorsch, P., and Witorsch, R.J., "Comments on EPA Review Draft Document 'Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders,' May, 1992," comments submitted to Science Advisory Board, U.S. Environmental Protection Agency, July 6, 1992 [7/30/93]

84. Wu, J.M., "Comments on the Draft Environmental Protection Agency Document: 'Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children,'" comments submitted to U.S. EPA public docket, 1990 [7/30/93]

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### III. UNPUBLISHED PUBLIC STATEMENTS

1. Bliley, T.J., Letter submitted to M. Lippmann, Institute of Environmental Medicine, New York University Medical Center, Tuxedo, NY, May 29, 1991 [7/30/93]
2. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, January 30, 1991 [7/30/93]
3. Bliley, T.J., Letter submitted to W.K. Reilly, EPA, Washington, DC, December 22, 1992 [7/30/93]
4. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, May 9, 1991 [7/30/93]
5. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, November 23, 1990 [7/30/93]
6. Bliley, T.J., Letter submitted to W. Blot, National Cancer Institute, Rockville, MD, May 29, 1991 [7/30/93]
7. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, September 18, 1990 [7/30/93]
8. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, November 1, 1990 [7/30/93]
9. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, May 17, 1990 [7/30/93]
10. Bliley, T.J., Letter submitted to W. Reilly, EPA, Washington, DC, June 6, 1990 [7/30/93]
11. Brown, K., "A Brief Summary of the Public Comments Submitted to the U.S. EPA in Response to the External Review Draft EPA/600/6-90/006A: Health Effects of Passive Smoking: Lung Cancer in Adults and Respiratory Disorders in Children," Science Advisory Board Meeting, December 4-5, 1990 [7/30/93]
12. Davis, D.L., Statement: Disinfection Byproducts Technical Workshop, The Resolve Center for Environmental Dispute Resolution, November 4-5, 1992, Washington, D.C. [7/30/93]
13. Dingell, J.D., Letter submitted to F. Press, National Academy of Sciences, Washington, DC, June 20, 1991 [7/30/93]
14. Feinstein, Alvan, Statement: "Rose Hearing", July 21, 1993 [8/20/93]

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- "Well, let me be clear, now. I made the comment, sir, I think when you were out of the room that the EPA here did not really do any research. Meta-analyses are not, in my opinion, generally doing research. The research is what is done when you go out and get the original data that were in the original studies that were being pooled. In my opinion, those original studies weren't all that well done and if the student were submitting it to me I would say, you know, 'Can't you do any better than this?'"

15. Flamm, W.G., Statement before the U.S. House of Representatives, Committee on Agriculture, Subcommittee on Specialty Crops and Natural Resources, "The Rose Hearing," July 21, 1993 [7/30/93]
16. Fox, J.C., "Statement in Opposition to AB 13," The Committee on Labor and Employment, California State Assembly, March 3, 1993 [7/30/93]
17. Gori, G.B., Statement before the U.S. House of Representatives, Committee on Agriculture, Subcommittee on Specialty Crops and Natural Resources, "The Rose Hearing," July 21, 1993 [7/30/93]
18. Gori, G.B., Statement before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, "The Waxman Hearing," July 21, 1993 [7/30/93]
19. LeVois, M., Statement before the U.S. House of Representatives, Committee on Agriculture, Subcommittee on Specialty Crops and Natural Resources, "The Rose Hearing," July 21, 1993 [7/30/93]
20. PM Press Packet, "Tobacco Group Sues EPA Over ETS Risk Assessment," June 22, 1993 [7/30/93]
21. Switzer, P., Statement before the U.S. House of Representatives, Committee on Agriculture, Subcommittee on Specialty Crops and Natural Resources, "The Rose Hearing," July 21, 1993 [7/30/93]
22. "Technopolitics," WNET-TV, New York, NY, December 12, 1992, Transcript [7/30/93]
23. Tozzi, J.J., Letter submitted to Drs. Raub, Young, San Martin, Fouts & Fraumeni, December 31, 1992 [7/30/93]
24. Tozzi, J.J., Letter submitted to Raymond Loehr, Ph.D., University of Texas, Austin, Texas, October 27, 1992 [7/30/93]

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25. Tozzi, J.J., Letter submitted to E. Bretthauer, EPA, Washington, DC, November 4, 1992 [7/30/93]
26. Tozzi, J.J., Letter submitted to M. Lippmann, Institute of Environmental Medicine, Tuxedo, NY, November 3, 1992 [7/30/93]
27. Tozzi, J.J., Letter submitted to E. Bretthauer, EPA, Washington, DC, December 4, 1992 [7/30/93]

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IV. DRAFT CRITIQUES OF THE EPA RISK ASSESSMENT (NOT PUBLIC DOMAIN)

CAVEAT: DO NOT QUOTE OR CITE THESE DOCUMENTS. THEY ARE NOT PUBLIC DOMAIN.

1. C&B, "EPA and Environmental Tobacco Smoke: Science or Politics?", February, 1993, Draft [7/30/93]
2. C&B, "Legal Memorandum: A Ban on Smoking in Federal Buildings is Not Required to Address Liability Concerns," April 18, 1993, Draft [7/30/93]
3. Gori, G., "Testimony of Dr. Gio Batta Gori on H.R. 881: Legislation to Ban Smoking in Federally Owned and Leased Buildings, April, 1993," U.S. House of Representatives, House Committee on Public Works and Transportation, Subcommittee on Public Buildings and Grounds, Draft [7/30/93]
4. Gori, G., "A Critical Appraisal of the Report on Environmental Tobacco Smoke Issues by the US Environmental Protection Agency on January 7, 1993," April 1993, Draft [7/30/93]
5. Gross, Alan J., "Uncertainties in Lung Cancer Risk Estimates Reported for Exposure to Environmental Tobacco Smoke," Department of Biostatistics, Epidemiology, and Systems Science, Medical University of South Carolina, Charleston, SC 29425-2503, January, 1993, Draft [7/30/93]
6. Huber, G.L., Brockie, R.E., Mahajan, V.K., "Environmental Tobacco Smoke," June 16, 1993, Draft [7/30/93]
7. Perske, M., "The EPA's Crusade Against Environmental Tobacco Smoke: Politics or Science?", January 5, 1993, Draft [7/30/93]
8. Philip Morris, "A Critical Look at the EPA Report on Environmental Tobacco Smoke," EPA/ETS White Paper, April, 1993, Draft [7/30/93]
9. SH&B, "Background Materials Regarding the U.S. Environmental Protection Agency's Revised Risk Assessment," Critique, Draft [7/30/93]
10. SH&B, "Summary of Criticisms on EPA Risk Assessment," January, 1993 [7/30/93]
11. Switzer, P., "A Critique of the EPA Report on Environmental Tobacco Smoke," House Committee on Agriculture, Subcommittee

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on Specialty Crops and Natural Resources, April, 1993, Draft [7/30/93]

12. Switzer, P., "A Critique of the EPA Report on Environmental Tobacco Smoke," March, 1993, Draft [7/30/93]
13. Tobacco Institute, "EPA's Risk Assessment on Environmental Tobacco Smoke: A Critique," January, 1993, Draft [7/30/93]
14. Tobacco Institute, "EPA Group A Carcinogen Classification: Practical Implications for the Workplace," January 15, 1993, Draft [7/30/93]
15. Tobacco Institute, "EPA Risk Assessments: The Credibility Gap," January 15, 1993, Draft [7/30/93]
16. Tobacco Institute, "Presentation on the 'Problems with the EPA Report'," March, 1993, Draft [7/30/93]
17. Tozzi, J., "Meta-Analysis of Epidemiologic Studies Improving the Methodology from ETS to EMF," March, 1993, Draft [7/30/93]

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## V. STATEMENTS MADE BY EPA OFFICIALS (INCLUDING THE SAB)

### 1. SAB Committee Meeting Transcripts, December 4, 1990 [7/30/93]

- Geoffrey Kabat: "If you want to make a causal interpretation, one has to acknowledge facts like the fact that one of the largest studies, the Varela and Janerich Study, which was apparently more thorough than most of the studies, fails to find any positive association for spousal smoking or for workplace exposure."  
"[Y]ou can't overcome problems like these with meta analysis."  
"[T]here's no acknowledgement in the report that one's dealing with a weak association."  
"I think classifying ETS as a Class A Carcinogen is maybe a little rash."
- Howard Rockette: "I would like to see more attention being given to the -- to other potential confounders . . . I do think that scientifically that's the key issue and the meta analysis does not solve that."
- David Burns: "The other point that I would make has been made several times, which is that the different [sic] between mainstream and side stream smoke are very real, they are very important."
- Victor Latics: "I would drop the Hirayama study unless you can defend it against the commands [sic] of Dr. Kilpatrick . . . If you read this critiques you'd be convinced that Hirayama's study should not be cited or not be depended on heavily in this report."

### 2. Safeguarding the Future. 3/91 [7/30/93]

- Expert Panel on the Role of Science at EPA: "Science should never be adjusted to fit policy, either consciously or unconsciously."

### 3. Science Advisory Board Committee Meeting on 1992 Draft Risk Assessment. 7/21/92 and 7/22/92 [7/30/93]

- Morton Lippmann: "Well, it's clear the Appendices need some careful re-examination, and in some cases, clarification."

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- Jonathan Samet: "I'm somewhat concerned about the discussion and handling of confounding. There is a discussion of what a confounder is that I feel is subsequently in fact ignored in the discussion of the literature."  
"I'm not comfortable with the dismissal of the role of diet in lung cancer in nonsmokers."

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